



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/691,012

10/22/2003

Ole Buchardt

ISIS-5299

5682

32650 7590 08/28/2009

WOODCOCK WASHBURN LLP
CIRA CENTRE, 12TH FLOOR
2929 ARCH STREET
PHILADELPHIA, PA 19104-2891

EXAMINER

BORIN, MICHAEL L

ART UNIT

PAPER NUMBER

1631

MAIL DATE

DELIVERY MODE

08/28/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/691,012	Applicant(s) BUCHARDT ET AL.	
	Examiner Michael Borin	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06/04/2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 34-36,38-41,43-45 and 47-73 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 34-36,38-41,43-45 and 47-73 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's filing of an Appeal Brief on 06/04/2009 is acknowledged and entered. However, upon further consideration and because of applicant's arguments, prosecution on the merits is being reopened with the issuing of the newly applied Non-Final office action as stated below.

A Supervisory Patent Examiner has approved of reopening prosecution by signing below.

/Marjorie Moran/
Supervisory Patent Examiner, Art Unit 1631

As a short summary, the enablement rejection is withdrawn, the art rejection of record is maintained. The priority of the claimed subject matter to the parent application is denied; as a result, a new ground of rejection over prior art is applied.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37.

The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been

Art Unit: 1631

increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

Status of Claims

1. Claims 34-36,38-41,43-45,47-73 are pending.

Priority

The parent application 08/108591 was closely reviewed. The instant subject matter is directed to method of *in vivo* treatment having the following limitations:

- broad genus of compounds addressed as “polyamide nucleic acid oligomer containing neutral amide backbone linkages”
- treatment of living cells
- *in vivo* treatment

The parent application 08/108591 does not provide sufficient support for use of such broad genus of compounds, does not disclose use for *in vivo* treatment of living cells.

Consequently, the claimed subject matter is not entitled to the effective filing date 11/22/1993 of parent application 08/109591.

Claim Rejections - 35 USC § 102.

Art Unit: 1631

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

2.(Maintained) Claims 34-36,41,48-51,58,59,65-68 are rejected under 35 U.S.C. 102(e) as anticipated by Summerton et al (US 5,142,047)

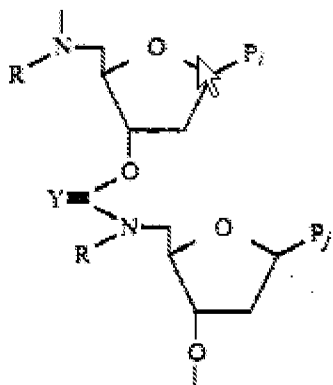
The instant claims are drawn to methods of treatment by *in vivo* administration of a polyamide nucleic acid oligomer containing neutral amide backbone linkages which is complementary to a target nucleic acid, under conditions wherein said oligomer engenders a biological response associated with said target. The claims specify that the administration is “extracellular”. Claims 34-36,38-41,43-47 are directed to method of “treating living cells”, whereas methods of claims 48-73 are directed to methods “comprising administering” said oligomer. Further, claims are directed to treating either cells, or mammals or organism (claims 34-36,38-40, claims 41-45,47, 58-64, and claims 65-73, respectively).

As the claims are directed either to extracellular administering *in vivo* or to treatment comprised of administering *in vivo*, it is Examiner’s position that any reference teaching *in vivo* administration of oligomer as claimed will read on “extracellular

administering *in vivo*" or on "treatment comprised of administering *in vivo*". As for the limitation "administering under conditions wherein said oligomer engenders a biological response associated with said target", again, it is Examiner's position that any reference teaching *in vivo* administration of oligomer as claimed (i.e., oligomer which is complementary to a target nucleic acid) is read as administering under conditions wherein said oligomer engenders a biological response associated with target nucleic acid to which the applied oligomer is complementary.

As such the following reference is considered to read on the invention as claimed.

Summerton et al (US 5,142,047)¹ teach therapeutic administration of polymer composition effective to bind to a single-stranded polynucleotide containing a preselected target sequence of bases. See Abstract. The composition is composed of linked-subunit heteromeric polymer molecules, such as polymer comprised of subunits "B" and connected by amide backbone linkages. A part of the polymer structure, for two moieties "B", oligomer B-B, is exemplified in col. 5:



¹ Exemplary reference of multiple patents of the same applicant

wherein, for $Y=O$, the formula demonstrates an “oligomer containing neutral amide backbone linkage”, and is a part of “polyamide nucleic acid oligomer” which contains “neutral amide backbone linkages”.

The reference addresses use of the polymer composition for inhibiting biological activity of a single-stranded polynucleotide (col. 7, lines 45-47), disease-specific mRNA in particular (paragraph bridging columns 16-17). As the polymers of Summerton are binding compounds having desired binding activity to selected target sequence (col. 5, lines 1-7, and col. 16, bottom), and a target sequence is a single-stranded polynucleotide (col. 4, bottom), the oligomers of 5,142,047 read on oligomers administered as per the instant invention.

With respect to claims 35,49,66 directed to detecting biological response, as argued by applicant, disclosure of use to bind *in vivo* binding to target polynucleotides inherently teach monitoring the organism and detecting a biological response (response of 01/09/2008, p. 8, last full paragraph).

With respect to claims 51,59,68 specifying that the administered oligomer has sequence specificity to nucleic acid that regulates the expression or encodes a polypeptide, the reference teaches that the oligomers are complementary to single-stranded polynucleotides (col. 7, lines 45-47), disease-specific mRNA in particular (paragraph bridging columns 16-17) or genes (col. 17, line 53).

Response to arguments

Applicant maintains that the compounds disclosed in Summerton et al contain urethane, rather than amide, linkage. Examiner disagrees. The instant claims do have

a structure of the compounds used; rather the claims use open language "containing" (which is equivalent to "comprising"): "containing neutral amide backbone linkages". As such the structure -O-CO-NR- in Summerton et al is viewed as containing amide (underlined) as instantly claimed.

3.(New) Claims 34-36,38-41,43-45,47-73 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Richelson et al. (US patent 6,472,209; effective filing date 10/17/1997).

As pointed out by applicant, the claims of Richelson et al. are copied in the instant application to provoke an interference. However, as the instantly claimed subject matter is not entitled to the effective filing date 11/22/1993 of parent application 08/109591 (see "Priority" section above), the effective filing date of the instant claims is 10/22/2003. Therefore, Richelson et al. is applied as prior art.

Prior art made of record

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Other patent of Richelson et al. is:

6,743,627 (filing data January 30, 1998), directed to method of treating an animal, said method comprising orally administering to said animal a polyamide nucleic acid oligomer containing neutral amide backbone linkages, which is complementary to a nucleic acid target, under conditions wherein said oligomer engenders a biological response associated with said target in a sequence specific manner. See claims 1-33.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Borin/
Primary Examiner, Art Unit 1631